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DOBRUSIN & THENNISCH PC
29 W LAWRENCE ST
SUITE 210
PONTIAC, MI 48342

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,745	SNYDER ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 21-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 21-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 03/01/2010.

Claims 11 and 21-35 previously presented. Claims 36-39 are currently added.

Claims 11, 21-39 are pending and included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11, 21, 24-26, 32, 33, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smedley et al. (US 7,163,543, currently listed on PTO 892) combined with Peyman (US 7,354,574, previously presented).

Applicant Claims

Present claim 11 is directed an implantable device, comprising:

a) an implantable elongated hollow glaucoma drainage tube including a solid walled plastic lumen having a lumen section that extends into the eye and wraps generally circularly around the cornea and includes a flow passage so that when the tube is implanted within an eye the tube has a first end located in a first portion of an eye and a second end located in a second portion of the eye and the flow passage spans between the first end and the second end; and

b) a sustained release medium including caprolactone and an antimicrobial within the interior of the lumen that is filled with the sustained release medium to define a head space passage that increases its degree of opening over time as matter is passed through the lumen; wherein the lumen has a circular cross section fixed inner and outer dimension, defining a lumen diameter, the tube includes a plurality of openings of a fixed size and shape, through which the sustained release medium escapes, and the sustained release medium comprises a solid material.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Smedley teaches glaucoma treatment by permitting aqueous to flow out of the anterior chamber of the eye through a stent to Schlem's canal with one end of the stent positioned in the anterior chamber and a second end positioned in the Schlem's canal (abstract; col.3, lines 36-47). The stent contains pharmaceuticals that reduce, inhibit or slow the effects of glaucoma and heals any injury of the eye (col.3, lines 17-31). The stent is made of biocompatible material that can be metal, i.e. solid, and is coated by therapeutic agent (col.7, lines 55-63). The stent has lumen that can be circular, and has plurality of side openings (col.8, lines 1-3, 12-20; figure 3). Smedley teaches that the device can be coated or loaded within interior location, such as pores, with a slow release therapeutic active substance that have prolonged effect on the local tissue surrounding the device (col.10, lines 31-38, 60-65). The coating is expected to cover the openings as required by claims 24, 32-34. The teaching of the reference that "the

therapeutic agent can be loaded in interior location of the stent", would have suggested inner surface of the lumen of the stent or within the wall. Regarding claim 38, Smedley teaches, in col.9, lines 36-46, flow restricted member that can be a polymer that reads on claim 38.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Smedley teaches loading of the device with slow release therapeutic agent and teaches interior loading, however, the reference does not explicitly teach sustained release caprolactone polymer as a release medium as instantly claimed by claim 11.

Peyman teaches implantable composition for treating ocular diseases (abstract). The composition comprises antimicrobial agent in polymer matrix of polycaprolactone contained in a diffusible walled reservoir providing sustained release composition formulated to release non-toxic therapeutic amount of the antimicrobial agent over the time (col.2, lines 9-15; col.3, lines 18-25, 42-48, 56-65).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide glaucoma treatment stent having lumen with one end positioned in the anterior chamber and a second end positioned in the Schlem's

canal that can be loaded in the interior with a slow release therapeutic active substance that have prolonged effect on the local tissue surrounding the device as taught by Smedley, and provide the therapeutic agent in a polymer matrix of polycaprolactone as taught by Peyman. One would have been motivated to do so because Peyman teaches that polycaprolactone matrix provides sustained release of the contained therapeutic agent in non-toxic therapeutic amount over the time. One would reasonably expect formulating glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent in order to slowly release non-toxic doses of the therapeutic agent to the surrounding and injured tissues.

Regarding the limitation of increase of the degree of opening of the head space passage as claimed by claim 11, 24, 32-33, and halting the eroded layers when the pressure is released, the combined teaching of Smedley and Peyman provides glaucoma drainage tube having in the interior a polymer composition comprising caprolactone, and it is expected that caprolactone will be eroded slowly to release the therapeutic agent, and bidegradation of the caprolactone will halt the erosion product, therefore forming the head space passage as the polymer degrades, and it is expected that by time and with erosion of the caprolactone matrix, more space is created in the stent lumen.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

5. Claims 22, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Smedley and Peyman and further in view of Bardenstein (US 4,743,255 previously recited).

The combined teaching of Smedley and Peyman are previously discussed as set forth in this office action.

However, the references do not teach radiologically detectable marker material as claimed by claims 22, 27 and 28.

Bardenstein teaches intraocular implantable material that can be incorporated with radio-opaque marker material for follow up using simple radiological technique without resorting to complex imaging techniques (col.1, line 64-col.2, line 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent as taught by the combined teachings Smedley and Peyman, and further add radio-opaque material that can be detected by radiology to the stent as taught by Bardenstein. One would have been motivated to do so because Bardenstein teaches that radio-opaque marker material helps follow up using simple radiological technique without resorting to complex imaging techniques. One would reasonably expect formulating glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent and radio-opaque marker material that helps follow up by simple radiology technique.

6. Claims 23, 29-31, 34-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Smedley and Peyman and further in view of Wong et al. (US 6,692,759 previously recited) as applied to claims 23, 29-30, 36, and over the combination of Smedley, Peyman and Bardenstein and further in view of Wong et al. as applied to claims 31, 34-35, 37 and 39.

The combined teaching of Smedley and Peyman, and the combined teachings of Smedley, Peyman and Bardenstein are previously discussed as set forth in this office action.

However, the references do not teach layered sustained release material as claimed by claims 23, 29-31, 34-37 and 39.

Wong teaches ocular implantable devices for sustained release of active substances including therapeutic agents to tissues adjacent to the area of implantation (abstract; col.3, lines 32-38; col.5, lines 17-20; col.8, lines 45-64). The implant is multi-layered to deliver two or more active agents to reach different surrounding regions and particularly useful for delivering two or more active substances (col.6, lines 58-63; col.9, lines 26-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent as taught by the combined teachings Smedley and Peyman, or provide glaucoma treatment stent having lumen loaded in the interior with polycaprolactone matrix containing therapeutic agent

and radio-opaque marker material as taught by the combination of Smedley, Peyman Bardenstein, and further formulate the matrix as a multilayered matrix as taught by Wong. One would have been motivated to do so because Wong teaches that multi-layered implantable delivery device is particularly useful for delivering one or more active substances to the surrounding regions. One would reasonably expect formulating glaucoma treatment stent having in the interior multilayered polycaprolactone matrix containing more than one therapeutic agent and further may have radio-opaque marker to provide more than one beneficial effect to the surrounding regions to patient in need.

Response to Arguments

7. Applicant's arguments filed 03/01/2010 have been fully considered but they are not persuasive.

Applicants argue:

a) Lack of Fact Findings:

> Applicants argue that the office failed to present facts showing where each and every element of claim 11 is taught. Specifically, the office action has failed to show where the references of record teach, "a solid walled plastic lumen having a lumen section that extends into the eye and wraps generally circularly around the cornea." The office action failed to show where "the sustained release medium comprises a solid material," "a sustained release medium including caprolactone and an antimicrobial within the interior of the lumen," and "wherein the lumen has a circular cross section fixed inner and outer dimension" is taught. The office action has failed to show where the references of record teach the elements of claims 21 and 26. Specifically, the office action has failed to show where "the lumen has open ends" is taught.

In response to this argument, it is argued that all the elements of the claims are taught by the combined teachings of the cited references. Smedley teaches clearly, col.3, lines 36-47, glaucoma treatment by permitting aqueous to flow out of the anterior

chamber of the eye through a stent to Schlem's canal **with one end of the stent positioned in the anterior chamber and a second end positioned in the Schlem's canal**. The stent is made of biocompatible material that can be metal, i.e. solid, and is coated by therapeutic agent. The stent has **lumen that can be circular, and has plurality of side openings** (col.8, lines 1-3, 12-20; figure 3). The term **"lumen" taught by the reference implied open ended as evident by the teaching of the reference that the aqueous flows out of the anterior chamber of the eye through a stent to Schlem's canal**, as required by claims 21 and 26. Peyman teaches implantable composition comprises antimicrobial agent in **polymer matrix of polycaprolactone** contained in a diffusible walled reservoir providing sustained release composition formulated to release non-toxic therapeutic amount of the antimicrobial agent over the time.

Regarding the limitation of "lumen wraps generally circularly around the cornea, as instantly recited by amended claim 11, applicants failed to show unexpected results obtained from this limitation over the prior art stent that effectively treats glaucoma by directed the aqueous flow out of the anterior chamber of the eye through a stent to Schlem's canal, as applicants have done. MPEP §2144.04 (IV)(B) similarly states that simply changing the shape of a device was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed invention was significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) Such is expressly evident in prior art teachings of

figure 3 of stent that can have different shape to accommodate between the anterior chamber and Schlem's canal.

Therefore, the is no lack of fact findings and each and every element of claim 11, and depending claims is taught either by the primary reference or by its combination with the secondary references as set forth in the rejections above.

b) Lack of Evidentiary Support for Fact Finding:

Applicants argue that the office action has not presented enough facts and evidence to support a prima facie obviousness rejection. For example, the office action rejected claim 11 stating, "The stent has lumen that can be circular, and has plurality of side openings FIG. 3 shows the lumen 7 is oval. Applicants believe that the evidence provided in the office action does not support the assertion that Smedley teaches "wraps generally circularly around the cornea." The office action allegedly presented facts to show that Smedley teaches the limitations of claims 24 and 32-34; however, the office action never states what reference contains these facts or where these facts are contained in a reference. Specifically, the office action states, "The coating is expected to cover the openings as required by claims 24, 32-34. The teaching of the reference that 'the therapeutic agent can be loaded in interior location of the stent', would have suggested inner surface of the lumen of the stent or within the wall." Applicants have searched both Peyman and Smedley for the location of the material quoted by the office action; however, Applications were unable to locate this language in either reference. Applicants invite the examiner to show where the either Peyman or Smedley contain the quoted language; however, Applicants believe that as stands the facts presented by the office action are not supported by evidence.

In response to these argument, it is argued that Smedley suggested circular opening in col.8, lines 12-16, wherein the reference teaches: "lumen 7.... May have cross-sectional shape that is oval, **circular** or other appropriate shape."

Regarding the limitation of "lumen wraps generally circularly around the cornea, as instantly recited by amended claim 11, applicants failed to show unexpected results obtained from this limitation over the prior art stent that effectively treats glaucoma by directed the aqueous flow out of the anterior chamber of the eye through a stent to

Schlem's canal, as applicants have done. MPEP §2144.04 (IV)(B) similarly states that simply changing the shape of a device was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed invention was significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) Such is expressly evident in prior art teachings of figure 3 of stent that can have different shape to accommodate between the anterior chamber and Schlem's canal.

Regarding the limitations of claims 24, 32-34, Smedley teaches that the device can be coated or loaded within interior location, such as pores, with a slow release therapeutic active substance that have prolonged effect on the local tissue surrounding the device (col.10, lines 31-38, 60-65). The coating is expected to cover the openings as required by claims 24, 32-34. The teaching of the reference that "the therapeutic agent can be loaded in interior location of the stent", would have suggested inner surface of the lumen of the stent or within the wall. Therefore, the limitations of claims 24 and 32-34 are taught by Smedley.

Therefore, the facts presented by the office action are clearly supported by evidence from the cited references. Further, in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in

the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

c) Improper Application of KSR:

Applicants argue that the office action has failed to present factual and/or evidentiary support for all of the rejections. Moreover, the office action has not presented evidence that all of the claims are obvious in view of the references of record and that the references are combinable. For example, claim 31 depends from claim 27. Claim 27 was rejected by the combination of Smedley and Peyman in view of Bardenstein. The office action failed to present any evidence showing that Wong is combinable with Smedley, Peyman, and Bardenstein. The office action simply states that Wong allegedly teaches the elements of claim 31 without presenting any evidence that Wong is combinable with Smedley and Peyman. Furthermore, the office action completely ignores additionally combining Wong with Bardenstein. Applicants do not believe that these four references are combinable.

In response t his argument, it is argued that the claims were misnumbered in the previous amendment resulting in confusion of the statement of the rejection. In any event all the claims are currently rejected and the numbers are corrected, no new art is applied. All the elements of the claimed invention are taught by combination of the prior art.

Regarding the limitation of "lumen wraps generally circularly around the cornea, as instantly recited by amended claim 11, applicants failed to show unexpected results obtained from this limitation over the prior art stent that effectively treats glaucoma by

directed the aqueous flow out of the anterior chamber of the eye through a stent to Schlem's canal, as applicants have done. MPEP §2144.04 (IV)(B) similarly states that simply changing the shape of a device was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed invention was significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) Such is expressly evident in prior art teachings of figure 3 of stent that can have different shape to accommodate between the anterior chamber and Schlem's canal.

Further, in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

> Applicants argue that the office action has not shown where any of these references teach: having a lumen section that extends into the eye and wraps generally circularly around the cornea, a solid walled plastic lumen, and a lumen has open ends. For example, Applicants do not believe it would be obvious for one skilled in the art to combine Smedley and Peyman with Bardenstien. Simply stated, Smedley teaches a

> treatment for ocular diseases (see title of the patent); whereas, Bardenstein "is directed to an improved intra-ocular device which can be readily located in the eye even after a subsequent (post-operative) condition or injury to the eye." Since Smedley does not incorporate the teachings of an "intra- ocular lens" into its present invention, Applicants do not believe that Smedley and Bardenstein are combinable. The office action has failed to clearly show any teaching, suggestion, or motivation that Smedley and Peyman are combinable with Bardenstein; thus, Applications believe that a proper prima facie obviousness rejection has not been presented.

Regarding the limitation of "lumen wraps generally circularly around the cornea, as instantly recited by amended claim 11, applicants failed to show unexpected results obtained from this limitation over the prior art stent that effectively treats glaucoma by directed the aqueous flow out of the anterior chamber of the eye through a stent to Schlem's canal, as applicants have done. MPEP §2144.04 (IV)(B) similarly states that simply changing the shape of a device was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed invention was significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) Such is expressly evident in prior art teachings of figure 3 of stent that can have different shape to accommodate between the anterior chamber and Schlem's canal.

Further it is argued that motivation to combine the cited prior art exists and clear statements of motivation were stated in the rejection as set forth in this office action. Additionally, the references are combinable because the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all the references are in the field of applicant's endeavor.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). See the rejections as set forth in this office action. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Finally, it is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and

references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG